

**UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA**

Endo Pharmaceuticals Inc., et al.,

Plaintiffs,

v.

Federal Trade Commission,

Defendant.

CIVIL ACTION: 2:16-cv-05599

2:16-cv-05600

Endo Pharmaceuticals Inc., et al.,

Plaintiffs,

v.

Federal Trade Commission,

Defendant.

**DECLARATORY JUDGMENT PLAINTIFFS' OPPOSITION TO MOTION
TO DISMISS**

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I. INTRODUCTION

In March 2016, the Federal Trade Commission (“FTC” or “Commission”) voted to sue Plaintiffs¹ in federal court. On March 30, 2016, the Commission acted on that final decision: it filed a complaint in this District against Plaintiffs, alleging violations of the FTC Act related to the drugs Lidoderm and Opana ER (the “Original Action”). Later, in response to Plaintiffs’ motions to sever the Original Action, the Commission unequivocally represented to this Court that it intended to *again* act on its final decision by voluntarily withdrawing its complaint, and refileing its claims in two other federal courts, should the Court grant Plaintiffs’ motion. *See* Dkt. 73, at 2, No. 16-cv-01440-PD (the FTC “intends to voluntarily dismiss and refile the two separate cases in [N.D. Ill. and N.D. Cal.]”). Indeed, the FTC was so intent on refileing that it asked the Court to transfer the claims to obviate its need to do so. *Id.*

The FTC now argues that its vote to sue Plaintiffs—while final enough to support filing a complaint with this Court, and final enough to support the factual representations made to this Court—is not sufficiently final for Plaintiffs’ declaratory judgment actions (the “Actions”) to proceed. But the FTC completed its administrative process when it voted to sue Plaintiffs in federal court; the bell

¹ Impax Laboratories, Inc. (“Impax”), Endo Pharmaceuticals, Inc. (“Endo”), and Watson Laboratories, Inc. (“Watson,” collectively the “Plaintiffs”).

has already been rung. Nor can the Commission un-ring that bell by suggesting that, in fact, it has not made “any decision as to how it will proceed” with its claims. Motion to Dismiss (“Mot.”) at 11. To begin with, that suggestion is flatly inconsistent with the Commission’s previous representations to this Court, and also with recent statements by the Director of the FTC’s Bureau of Competition.² Moreover, actions speak louder than words: the FTC’s action remains final regardless of what changes in course the FTC now says it is considering. The Commission cannot render the Actions no longer ripe simply because it claims to be unsure of its future strategic path.

Contrary to the FTC’s claims, Plaintiffs may seek judicial review of this indisputably ripe controversy under either the Declaratory Judgment Act (“DJA”) or the Administrative Procedure Act (“APA”). Where, as here, a defendant could have filed a federal cause of action against the declaratory judgment plaintiffs—thus creating a concrete case or controversy—the DJA allows those plaintiffs to seek a declaration of their rights under the same federal cause of action, without waiting for the FTC to actually file it (as the FTC has threatened to do), essentially “borrowing” the FTC’s threatened cause of action. Thus, the case and controversy

² See FTC, The Competition List for 2016 (Jan. 3, 2017), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2017/01/competition-list-2016?utm_source=govdelivery (listing the Original Action as a “top ten FTC-related antitrust development[]” of 2016 only days after moving to dismiss).

between Plaintiffs and the FTC regarding the FTC's authority to sue under Section 13(b) to seek disgorgement or restitution, and the timeliness of its claims—all of which has been briefed—need wait no longer for judicial review.

These Actions satisfy the APA's requirements, which also provides Plaintiffs a cause of action. There can be no question that the FTC's decision to sue Plaintiffs in federal court—rather than to file an administrative action—is a “final” agency action. By voting to sue in federal court, the FTC ended its administrative process, and ceded its claims to the judicial branch, allowing no additional administrative recourse.

No matter the avenue, the Actions are ripe for judicial determination because they present a case and controversy for which there is no additional administrative redress, and which the parties have fully briefed before this Court. The Actions challenge what was clearly the final step of the FTC's administrative process. Thus, the Actions effectuate the purpose and policies underlying both the DJA and the APA: to allow timely review of a final agency action without additional delay.

II. BACKGROUND

The FTC began investigating two separate patent litigation settlements—one regarding Lidoderm, the other involving Opana ER—in early 2014. The agreements shared no factual nexus beyond Endo being a party to each. The FTC investigated these settlements for over two years before FTC staff recommended

that the Commission bring a lawsuit in federal court under Section 13(b) of the FTC Act. The Commissioners voted to follow this recommendation, 3-1, terminating the FTC's administrative process and ending the Commission's role as an administrative body in the matter.

The Commission filed the Original Action in this Court on March 30, 2016. Dkt. 1, No. 16-cv-01440-PD. Plaintiffs moved to sever the claims related to Lidoderm from those related to Opana ER. Dkts. 57-58, No. 16-cv-01440-PD. Plaintiffs also moved to dismiss the FTC's suit on the grounds presented in these Actions. Dkt. 69, No. 16-cv-01440-PD. The FTC opposed. Dkt. 89, No. 16-cv-01440-PD. Plaintiffs' motion to dismiss presented—and via an opposition, reply, and sur-reply, the parties fully briefed—the issues raised in the current Actions. Dkts. 69, 89, 110, 112 No. 16-cv-01440-PD. The FTC also opposed the motions to sever, and in its opposition asked that if the Court did sever the claims, it also transfer the cases to the venues in which private multidistrict litigation is ongoing. Dkt. 73, at 2, No. 16-cv-01440-PD. Although Plaintiffs argued the FTC lacked authority to sue in federal court, the FTC never wavered in its intention to do so. Indeed, the FTC stated to the Court that, if the Court were to sever the claims without transferring, then the Commission would “voluntarily dismiss and refile the two separate cases” in the MDL courts. *Id.* This Court severed the claims, but refused to transfer them. Dkt. No. 120, No. 16-cv-01440-PD. The FTC then

voluntarily dismissed the claims, ostensibly in preparation to refile the complaints in the MDL districts. Dkt. 121, No. 16-cv-01440-PD.

After the FTC withdrew its claims, Plaintiffs sought declaratory judgments on the very issues already briefed in the Original Action. Dkt. 1, No. 16-cv-05600-PD; Dkt. 1, No. 16-cv-05599-PD. The FTC now seeks dismissal, contending that Plaintiffs must satisfy the APA, and that because “[t]he FTC Commissioners have not yet decided whether to bring enforcement proceedings against plaintiffs,” the Actions are not ripe. Mot. at 1. The FTC is incorrect.

III. THIS COURT NEED NOT APPLY THE ADMINISTRATIVE PROCEDURE ACT TO HEAR THESE ACTIONS

The circumstances of this case—including the FTC’s vote to sue Plaintiffs in federal court under the FTC Act—create a justiciable cause of action under the DJA. The FTC not only initiated litigation under the FTC Act, it also unequivocally represented to this Court that it intended to refile its claims in other federal courts if, as occurred, this Court severed the Original Action. This created an actual controversy between the parties regarding the FTC’s statutory authority to assert, in federal court, the same claims at issue in its Original Action and threatened actions. Because the FTC sued Plaintiffs in federal court and said it would do so *again*, Plaintiffs may seek a federal court declaration that the FTC does not have authority to proceed with that litigation under Section 13(b) of the FTC Act, that it cannot seek disgorgement, and that its Opana ER claims are barred

by the statute of limitations. Plaintiffs need not wait for the FTC to refile.

A. The Declaratory Judgment Act Allows Plaintiffs To Bring These Actions Because There Is A Concrete Case And Controversy Between The Parties Under The FTC Act.

The DJA, 28 U.S.C. § 2201, allows parties, under an imminent threat of litigation, to bring that controversy before a court without waiting for the putative plaintiff to sue.³ Specifically, the DJA provides:

In a case of actual controversy within its jurisdiction, . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

28 U.S.C. § 2201(a). Plaintiffs’ Actions are consistent with the purpose of the DJA, which is “to enable a person caught in controversy to obtain resolution of the dispute, instead of being forced to await the initiative of the antagonist.” *Hunt Mfg. Co. v. Fiskars Oy AB*, No. Civ.A. 97–2460, 1997 WL 667117, at *3 (E.D. Pa. Oct. 2, 1997) (internal quotation omitted). The DJA enables parties facing

³ Federal court jurisdiction is also required to bring a case in federal court under the DJA. The controversy raised in the Actions relates directly to the FTC’s authority to file litigation under Section 13(b) of the FTC Act, and therefore arises under federal law for purposes of 28 U.S.C. § 1331. *See Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 848 (2014) (quoting *Pub. Serv. Comm’n of Utah v. Wycoff Co.*, 344 U.S. 237, 248 (1952) (noting the “character of the threatened action” is what is relevant for determining federal court jurisdiction) (internal quotations omitted)). When it filed the Original Action, the FTC acknowledged that “[t]his Court has subject matter jurisdiction over this action pursuant to [among other statutes], § 1331.” Dkt.1, Compl. ¶ 5, 16-cv-01440-PD.

threatened federal claims to take the initiative and seek a declaratory judgment.

See HPF, LLC v. Nu Skin Enters., Inc., No. Civ.A. 99–CV–1505, 1999 WL 782573, at *3 (E.D. Pa. Sept. 28, 1999) (“Courts should give effect to the Federal [DJA’s] policy of providing persons threatened with litigation a means to determine their rights.” (citation omitted)).

The FTC’s course of conduct, and explicit representations to the Court, pose an imminent threat of litigation against Plaintiffs under Section 13(b) of the FTC Act. Thus, whether the FTC has authority to bring a suit is an actual, justiciable controversy arising under federal law (and therefore a federal cause of action). The FTC precipitated this issue by suing Plaintiffs in the first instance, after which the issue was briefed to this Court. Plaintiffs need not wait for the FTC to make up its mind about litigation already once filed, and twice threatened, under the DJA.

B. The DJA, Via The FTC Act, Provides A Cause Of Action.

The FTC’s suits under the FTC Act—both actual and threatened—provide Plaintiffs with a federal cause of action to support these declaratory judgment suits. “If there is an underlying ground for federal court jurisdiction, the Declaratory Judgment Act allow[s] parties to precipitate suits that otherwise might need to wait for the declaratory relief defendant to bring a coercive action.” *Household Bank v. JFS Grp.*, 320 F.3d 1249, 1253 (11th Cir. 2003) (internal citation omitted). Indeed, the DJA allows “a party to bootstrap its way into federal court by alleging

the imminence of another party’s federal action against it.” *Superior Oil Co. v. Pioneer Corp.*, 706 F.2d 603, 607 (5th Cir. 1983). The Third Circuit has acknowledged that “[f]ederal courts have regularly taken original jurisdiction over . . . suits in which, if the declaratory judgment defendant brought a coercive action to enforce its rights, that suit would necessarily present a federal question.” *Metro. Life Ins. Co. v. Price*, 501 F.3d 271, 277 n.4 (3d Cir. 2007) (citing *Franchise Tax Bd. of State of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 19 (1983)). The underlying principles are the same whether a private plaintiff or a federal agency threatens litigation.

The circumstances in *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, are particularly instructive. 134 S. Ct. 843 (2014). In *Medtronic*, the declaratory judgment plaintiff faced a potential claim of patent infringement, and thus sought a declaration that its products did not infringe. *Id.* at 847. The Supreme Court ruled that the declaratory judgment plaintiff could bring the action even though the Patent Act did not contemplate suits by alleged infringers (*i.e.*, there was no “independent” cause of action for infringers):

The relevant question concerns the nature of the threatened action in the absence of the declaratory judgment suit. . . . [The declaratory judgment defendant] could terminate the license and bring an ordinary federal patent law action for infringement. . . . Consequently, this declaratory judgment action, which avoids that threatened action, also ‘arises under’ federal patent law.

Id. at 848 (citation omitted). Because the threatened action arose under federal law

(*i.e.*, the Patent Act), the Court held that the plaintiff could seek a declaratory judgment. The same holds true here: the FTC has brought (and has threatened to bring again) federal suits against Plaintiffs under Section 13(b), and thus Plaintiffs may seek relief under the DJA to avoid those threatened actions.

In sum, under *Medtronic* and numerous lower court cases before and after that decision, a declaratory judgment plaintiff does not need an *independent* cause of action, so long as the its complaint includes facts sufficient to establish that the *defendant* could or would have filed a lawsuit under federal law. *See Browne v. Zaslow*, 103 F. Supp. 3d 666, 673-74 (E.D. Pa. 2015) (“Federal question jurisdiction exists in a declaratory judgment action if the plaintiff has alleged facts. . . which demonstrate that the defendant could file a coercive action arising under federal law.”); *see also Bell Atl. Corp. v. MFS Commc’ns Co.*, 901 F. Supp. 835, 840 (D. Del. 1995); *GNB Battery Techs., Inc. v. Gould, Inc.*, 65 F.3d 615, 619 (7th Cir. 1995). Plaintiffs’ complaints contain a quintessential example of sufficient fact: they allege the FTC has already brought (and has threatened to bring again) federal suits against Plaintiffs under Section 13(b). Thus, Plaintiffs may challenge the suits under the DJA without waiting for the FTC to refile. *See id.*⁴

⁴ The cases upon which the FTC relies stand for the unremarkable point that *if* the federal court would not have jurisdiction over the issue in dispute between the parties, *then* the DJA does not provide a standalone basis for federal jurisdiction. *See Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 673-74 (1950) (where

C. There Is A Ripe Controversy Between The Parties.

The DJA also requires “a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (citation omitted). This requirement is satisfied so long as litigation is implied. As is the case here, where the declaratory judgment defendant has *previously brought*, and has *threatened litigation*. See *Simmonds Aeroaccessories, Ltd. v. Elastic Stop Nut Corp. of Am.*, 257 F.2d 485, 490 (3d Cir. 1958); *Certainfeed Corp. v. Cellulose Insulation Mfrs. Ass’n*, No. 02–CV–6691, 2003 WL 1562452, at *1 n.5 (E.D. Pa. Mar. 24, 2003) (“[T]he threat of infringement litigation under the Act can be made directly or indirectly. . . .”). The FTC cannot rely on *Swish Mktg., Inc. v. FTC*, 669 F. Supp. 2d 72 (D.D.C. 2009), to suggest a different conclusion. That case involved an FTC threat to file suit, and the FTC conceded in its briefing that “[i]f and when the FTC institutes a Section 13(b)

the underlying dispute between the parties was a breach of contract claim not based on federal law, federal jurisdiction extended only to the defendant for which there was diversity); *Harris Cnty. Tex. v. MERSCORP Inc.*, 791 F.3d 545, 552 (5th Cir. 2015) (no federal law was at issue, and the relevant state law did not allow *either* party to sue); *Davis v. United States*, 499 F.3d 590, 594, 596 (6th Cir. 2007) (where plaintiff had no cause of action under the Illegal Immigration Reform and Immigrant Responsibility Act and potential coercive action by declaratory judgment defendant was “too speculative to support standing,” asserting a claim under the DJA could not create a justiciable controversy). These cases are inapposite because this Court clearly has jurisdiction over the issues disputed by the parties, and there is nothing speculative about the FTC’s coercive claims.

enforcement action [*i.e.*, a federal court action] against Plaintiffs, the Section 13(b) remedial issues could become ripe” for declaratory judgment. Defendant’s Memorandum in Support of its Motion to Dismiss at 19, *Swish Mktg., Inc. v. FTC*, No. 09-cv-0921 (D.D.C. 2009). Here, of course, the FTC “instituted a Section 13(b) enforcement action” and thus the controversy could scarcely be riper.

D. Discretionary Factors Weigh Heavily In Favor of Exercising Jurisdiction To Hear The Declaratory Judgment Claims.

Where there is a justiciable case or controversy between the parties, courts look to a number of non-exclusive factors to decide whether to exercise discretion to hear the case. *See Reifer v. Westport Ins. Corp.*, 751 F.3d 129, 140 (3d Cir. 2014).⁵ These factors weigh heavily in favor of maintaining the Actions.

1. The FTC Is Guilty Of Procedural Fencing, Not Plaintiffs.

The irony of the FTC’s argument regarding “procedural fencing,” Mot. at 20, cannot be overstated. Plaintiffs want only to finish what the FTC started, *in the forum where the FTC started it*. This is not “forum manipulation.” The FTC would have this Court operate in a vacuum and ignore these inconvenient facts, but

⁵ The discretionary factors include: (1) the likelihood that a federal court declaration will resolve the uncertainty of obligation which gave rise to the controversy; (2) the convenience of the parties; (3) the public interest in settlement of the uncertainty of obligation; (4) the availability and relative convenience of other remedies; (5) a general policy of restraint when the same issues are pending in a state court; (6) avoidance of duplicative litigation; (7) prevention of the use of the declaratory action as a method of procedural fencing or as a means to provide another forum in a race for res judicata. *Reifer*, 751 F.3d at 146.

there is no merit to the Commission's manipulation charge.

Plaintiffs' Actions present none of the elements that indicate forum shopping. The Actions have not "disturbed" nor "deprive[d]" the FTC of its "traditional choice of forum and timing," *id.* at 21, because ***the FTC chose*** this forum. There was no "disorderly race to the courthouse," *id.*, because the ***FTC sued first in this district.*** And Plaintiffs did not seek to "acquire a favorable forum," *id.*, because these Actions accept the FTC's initial choice of venue.

The FTC cites cases that purportedly immunize Rule 41(a) voluntary dismissals from accusations of forum shopping. But those decisions do not account for the unusual facts presented here. To the extent they are applicable at all, they support maintaining, not dismissing the Actions. For example, the court in *Swedberg v. Marotzke* held that plaintiff's Rule 41(a) voluntary dismissal was not forum shopping, in part because the defendant had not "made a significant investment in the lawsuit." 339 F.3d 1139, 1145 (9th Cir. 2003). But here, the parties ***invested significantly*** in the Original Action: they fully briefed an extensive motion to dismiss (including a sur-reply) involving the exact issues raised in these Actions, negotiated a protective order and ESI protocol, exchanged Rule 26(f) reports, exchanged initial disclosures, served discovery requests, produced documents and interrogatory responses from the Lidoderm MDL, engaged in numerous meet-and-confers, and litigated extensively over the FTC's

decision to bring the Lidoderm and Opana ER claims in a single case. These significant investments—and the “forum-shopping” factors generally—counsel decidedly in favor of this Court exercising jurisdiction over Plaintiffs’ Actions.⁶

2. There Is No Parallel Proceeding Pending.

Courts consider “the existence of a pending parallel proceeding” when evaluating declaratory judgment actions because “an absence ‘militates significantly in favor of exercising jurisdiction.’” *AXIS Ins. Co. v. PNC Fin. Servs. Grp., Inc.*, 135 F. Supp. 3d 321, 331 (W.D. Pa. 2015) (quoting *Reifer*, 751 F.3d at 144); *see also Martin v. Zurich Am.*, No. 1:15-CV-02118, 2016 WL 3551481, at *3 (M.D. Pa. June 30, 2016). There is no parallel proceeding here.

The FTC’s claim that Plaintiffs are attempting to “preempt a potential FTC enforcement action,” Mot. at 9, is meritless: one cannot preempt something that has already occurred. Plaintiffs seek only to resolve issues already briefed before this Court, and to preserve the efficiency of having a single court rule on these narrow legal issues.

3. It Is More Convenient To Decide These Issues In The Court In Which They Have Already Been Fully Briefed.

The next factor—convenience—also weighs decidedly in favor of this Court

⁶ The FTC cites *Bechuck v. Home Depot U.S.A., Inc.*, which held that a Rule 41(a) withdrawal was not a predicate for judicial sanctions. 814 F.3d 287, 292-93 (5th Cir. 2016). The decision does not support the FTC’s argument that its initial choice of venue is irrelevant.

maintaining jurisdiction. It would be far more convenient for the Court and the parties to maintain these Actions in this Court where the issues have already been fully briefed. *See Scottsdale Ins. Co. v. RSE Inc.*, 303 F.R.D. 234, 240 (E.D. Pa. 2014) (“[T]he parties are already before us, and thus convenience weighs in favor of exercising our jurisdiction.”). By contrast, allowing the FTC to shunt these issues from a single court to the two different districts where related, private litigation is ongoing will be *inefficient* because the Actions present purely legal issues not relevant to those cases and with which those courts are unfamiliar. *See infra* Section IV.B.2. Allowing the FTC to refile its claims in the MDL jurisdictions, as it has threatened, would disrupt those actions, which are already far beyond the motion to dismiss stage at which the parties would address these issues. Indeed, the parties in the Lidoderm MDL have already completed fact discovery and a trial date is set for later this year. Dkt. 645, 14-md-2521 (N.D. Cal. Dec. 29, 2016). The Opana ER matter has been in discovery for nearly two years. Dkt. 655, 14-md-2521 (N.D. Ill. Jan. 12, 2017). Finally, if the FTC believed coordination with the MDL courts would have been most efficient, it could (and should) have filed there originally.

4. It Is In The Public Interest To Define The Authority Granted To The FTC Under Section 13(b) And Preserve Judicial Resources.

Efficient resolution of uncertainty is in the public interest. *See, e.g., Fischer & Porter Co. v. Moorco Int’l Inc.*, 869 F. Supp. 323, 327 (E.D. Pa. 1994). Here, it

is in the public interest to resolve the uncertainty regarding the scope of the FTC's authority. It is also in the public interest to preserve vital judicial resources and to avoid piecemeal litigation spread across the country. *See infra* Section III.D.5.

5. While These Actions May Not Settle The Entire Dispute In All Circumstances, The Actions Will Prevent Duplicative And Piecemeal Litigation.

The FTC's argument that this Court should dismiss the Actions because additional litigation might occur if the FTC prevails turns the logic of this factor on its head. The FTC *itself* has promised additional litigation if these Actions are not heard; that is precisely what Plaintiffs' Actions seek to prevent.

The FTC primarily relies on *Morgan Drexen, Inc. v. Consumer Fin. Prot. Bureau*, which makes clear that this discretionary factor aims to prevent "piecemeal litigation." 785 F.3d 684, 697 (D.C. Cir. 2015); *see also* Mot. at 19. But avoiding vexatious, piecemeal litigation is *precisely why* the Court should hear the Actions. Resolving the Actions could resolve the parties' dispute in one fell swoop and prevent any further federal court litigation—piecemeal or otherwise—by deciding issues that have already been fully briefed before this Court. If these Actions are dismissed, by contrast, the FTC has promised that this litigation would proliferate—piecemeal—in two additional federal courts. *See* 13 Wright, Miller & Cooper, Federal Practice and Procedure § 4403 (noting goal to prevent "the

corrosive disrespect” that comes from “inconsistent results”).⁷

The FTC also argues that Plaintiffs could “raise all of their claims as defenses in the [future] enforcement proceedings.” Mot. at 20. But of course, Plaintiffs *did just that in their motion to dismiss the Original Action*. Dkt. 69, No. 16-cv-01440-PD. By withdrawing the Original Action, the FTC derailed the normal course of litigation. Requiring Plaintiffs to again raise these “defenses” in two additional courts for no reason, save that the FTC has changed its mind, would create needless duplication by forcing the parties to file redundant motions, repeat arguments, raise issues already briefed before this Court, and require additional courts to consider those arguments. This result can and should be avoided.

IV. THE COMMISSION’S VOTE TO SUE IN FEDERAL COURT CONSTITUTES A FINAL AGENCY ACTION RIPE FOR JUDICIAL DECISION UNDER THE APA.

As explained above, Plaintiffs do not need an independent cause of action to seek declaratory judgments, which are properly brought under the DJA. Likewise, a claim under the APA is not the sole route to relief. But if the Court looks to the APA, these Actions satisfy its requirements because they challenge the

⁷ The FTC also relies upon *Swish Marketing*, but that case contradicts the FTC. The court concluded, “[e]ven if the Court provides the requested declaratory relief, the controversy between the parties is likely to continue, resulting in substantial inefficiencies for both the parties and the judicial system.” 669 F. Supp. 2d at 78. Here, the opposite is true: “if the Court provides the requested declaratory relief, the controversy between the parties” will be over in the federal courts.

Commission’s “final” agency action, and present a ripe controversy to this Court.⁸

A. The FTC’s Vote To File A Federal Suit—And Subsequent Reiteration Of Its Intent To Pursue Those Claims—Is Final Agency Action.

An agency action is “final” and therefore reviewable under the APA if it “marks the consummation of the agency’s decisionmaking process . . . from which legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 178-79 (1997) (citations omitted). Courts “begin with the strong presumption that Congress intends judicial review of administrative action.” *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986); *see also Commw. of Va. v. Bowen*, 680 F. Supp. 228, 234 (W.D. Va. 1988) (“a strong presumption of reviewability” exists because “Congress intended that the APA provide a judicial safety net for review”). They apply a flexible standard that allows courts to use their common sense. *See U.S. Army Corps of Eng’rs v. Hawkes Co.*, 136 S. Ct. 1807, 1815 (2016); *State Farm Mut. Auto. Ins. Co. v. Dole*, 802 F.2d 474, 479 (D.C. Cir. 1986). Here, common sense plainly dictates that the Actions may proceed.

First, the Commission’s vote to sue Plaintiffs in federal court represents the “consummation” of its administrative process; there is no additional administrative

⁸ Not only is the FTC’s decision to sue a “final” agency action, Plaintiffs have “no other adequate remedy in a court.” 5 U.S.C. § 704. For the reasons explained in Section Part III.D.5, *supra*, forcing Plaintiffs to litigate the FTC’s authority to bring federal suit in two different suits pending in two separate courts is not an adequate remedy.

step left for the Commission to take after it votes. *See Sackett v. EPA*, 132 S. Ct. 1367, 1372 (2012) (compliance order “marks the ‘consummation’ of the agency’s decisionmaking process” because there was no additional opportunity for agency review); *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 437 (D.C. Cir. 1986) (action was “final” where agency “gave no indication” that there would be “further agency consideration or possible modification”). The FTC’s argument that its vote to file a federal lawsuit “does not mark the consummation of anything,” but instead “marks the *initiation* of a process” misses the point. *See* Mot. at 12. The process initiated by the suit was *judicial*, not administrative. After it files a federal suit, the Commission is no longer in the position of deciding “whether a party’s conduct is lawful,” but has ceded that issue to a court. In other words, once the Commission has voted to sue in federal court, its role fundamentally shifts from that of an administrative agency to that of a litigant—*i.e.*, the agency exchanges its administrative hat for an adversarial one. Nor is there any question that “legal consequences”—namely, forcing Plaintiffs to defend themselves against the FTC’s claims—flowed from the Commission’s decision to bring suit.

This situation is even more suited for judicial review than the typical APA case, in which a party is caught in the dilemma of complying with a new regulation or facing an enforcement action. Here, Plaintiffs face the legal consequence only threatened in those cases: a government enforcement suit. *Cf. Wearly v. FTC*, 616

F.2d 662, 667 (3d Cir. 1980) (“Wearly was under no compulsion to either turn over the documents to the FTC or suffer civil or criminal penalties as a result.”). FTC staff’s tactical decision to withdraw the Original Action does not (and cannot) alter the finality of the Commission’s vote authorizing FTC staff to file suit, particularly given the FTC’s representation to the Court that it intended to refile its actions.

See Sackett, 132 S. Ct. at 1372 (“The mere possibility that an agency might reconsider . . . does not suffice to make an otherwise final agency action nonfinal.”). Indeed, less than two weeks ago, after moving to dismiss the Actions, the FTC touted its enforcement action against Plaintiffs. *See supra* note 2.

For these reasons, Plaintiffs’ Actions differ fundamentally from the cases cited by the FTC, which hold—consistent with the APA’s underlying policy—that parties may not use the DJA to disrupt administrative processes.⁹ For example, in

⁹ None of the cases upon which the FTC relies involve a situation where the agency decided to forego administrative proceedings, instead proceeding to federal court. *See, e.g., FTC v. Standard Oil Co.*, 449 U.S. 232 (1980) (FTC had issued administrative proceedings that were still pending when Standard Oil filed declaratory judgment claim); *Chehazeh v. Attorney Gen.*, 666 F.3d 118 (3d Cir. 2012) (petitioner’s APA action was ready for review where Board of Immigration Appeals had initiated—and already concluded—administrative removal proceedings were open and ongoing); *Gen. Fin. Corp. v. FTC*, 700 F.2d 366 (7th Cir. 1983) (FTC’s pre-suit administrative investigation was ongoing when plaintiff filed suit to quash FTC civil investigative demands for testimony); *LabMD, Inc. v. FTC*, 776 F.3d 1275 (11th Cir. 2015) (FTC had initiated administrative proceedings that were ongoing when plaintiff filed federal court action challenging FTC’s power to investigate the subject matter of the proceedings); *Ukiah Valley Med. Ctr. v. FTC*, 911 F.2d 261 (9th Cir. 1990) (FTC had filed administrative

FTC v. Standard Oil Co. of Cal., the Supreme Court held that the Commission’s decision to file an **administrative** complaint was not a final agency action. 449 U.S. 237, 246-47 (1980). But the Court emphasized that an administrative complaint—unlike a federal court complaint—is “a determination only that adjudicatory proceedings will commence,” which could include an “appeal [of] an adverse decision . . . to the full Commission” for further agency action. *Id.* at 241. Unlike filing a complaint in federal court, filing an administrative action merely continues the administrative process.

The FTC’s reliance on *Wearly* is similarly misplaced because that case involved a declaratory judgment action brought ***in the middle of*** an FTC investigation, not at its conclusion. 616 F.2d at 663. The declaratory action at issue in that case was deemed a “[r]esort to a court by recipients of investigative subpoenas ***before an action for enforcement has commenced.***” *Id.* at 665 (emphasis added). Thus, *Standard Oil* and *Wearly* stand for the uncontroversial proposition that declaratory judgment plaintiffs may not interrupt ongoing FTC administrative processes by bringing declaratory judgment actions.¹⁰ Here, by

complaint and proceedings were ongoing); *Hindes v. FDIC*, 137 F.3d 148 (3d Cir. 1998) (FDIC issued notification of noncompliance but needed to hold administrative hearings and had not made a final agency action).

¹⁰ The other cases cited by the FTC on this add nothing new. The FTC cites them for the proposition that “courts have dismissed claims seeking declaratory or injunctive relief *to preempt the FTC’s ordinary enforcement processes.*” Mot. at 9

contrast, the FTC chose to forego continued administrative processes in favor of a judicial enforcement action. At that point, the FTC became an ordinary litigant that freely submitted itself to the decisionmaking authority of the judiciary.¹¹

The FTC's administrative processes make this distinction clear. Had the FTC sued Plaintiffs in "Part III" administrative court, the matter would have remained under the Commission's jurisdiction. An administrative law judge would have held an evidentiary hearing and reached a preliminary decision. Then, the defendants could have appealed that decision to the Commission for *de novo* review, which would have required the Commissioners to review the record and vote—*for a second time*—to affirm or reverse the administrative law judge's findings. Only after this final vote could the defendants seek redress in a federal appellate court. But here, the FTC chose to relinquish jurisdiction immediately by asking a federal court to enforce its final administrative determination.¹²

(emphasis added). These cases are similarly inapposite because the FTC's administrative processes were completed.

¹¹ Commissioner Ohlhausen dissented for this reason. She believed the Commission should retain jurisdiction by filing an administrative complaint to permit the Commission to "advance the law." *In the Matter of Endo Pharm. Inc.*, No. 141-0004, Dissenting Statement of Commissioner Maureen K. Ohlhausen, (Federal Trade Commission, Mar. 31, 2016), *available at* https://www.ftc.gov/system/files/documents/public_statements/942513/160331endostatement.pdf.

¹² The FTC's decision to sue in federal court and seek monetary relief is a final agency action for yet another reason: it represents an interpretation of Section 13(b) of the FTC Act that has been challenged by Plaintiffs. And "an agency's

B. The Claims In The Declaratory Judgment Actions Are Ripe Under The APA.

“[T]he ripeness doctrine requires a pragmatic and commonsense application,” *Eagle-Picher Indus., Inc. v. EPA*, 759 F.2d 905, 918 (D.C. Cir. 1985), and its “basic rationale” is to “prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 148-49 (1967). These concerns do not apply here, and common sense dictates that the Actions are ripe for adjudication.

These Actions do *not* involve “abstract disagreements.” The FTC brought a federal lawsuit raising the very questions presented in the Actions in federal court in the first instance. The issues raised were sufficiently concrete for the FTC to fully brief them in federal court only a few months ago. The FTC cannot retroactively destroy ripeness after the Plaintiffs’ Actions were filed by suggesting—when faced with declaratory judgment suits—that it might not

interpretation of its governing statute, with the expectation that regulated parties will conform to and rely on this interpretation, is final agency action fit for judicial review.” *Ciba-Geigy Corp.*, 801 F.2d at 438 (citation omitted); *accord Philip Morris USA Inc. v. FDA*, No. 15-cv-1590 (APM), 2016 WL 4378970, at *11 (D.D.C. Aug. 16, 2016).

actually refile its claims in other federal courts.

At the time Plaintiffs commenced these Actions, the FTC had represented unequivocally that it planned to refile its claims in two separate federal jurisdictions. The FTC even asked this Court to transfer its cases to prevent any break in the litigation. Such a clear statement of intent renders these Actions ripe for judicial review before ever reaching the *Abbott Labs* factors cited by the FTC—*i.e.*, the legal nature of the claim and the hardship created by not hearing the claim. Nonetheless, the Actions are ripe under these factors as well.

1. The Declaratory Judgment Actions Raise Purely Legal Questions.

A purely legal question, such as “whether the statute was properly construed,” is ripe for review. *See Abbott Labs.*, 387 U.S. at 149. Here, Plaintiffs have raised purely legal questions, namely “whether the Federal Trade Commission Act [] authorizes the FTC to bring federal court litigation—as opposed to administrative proceedings—to challenge conduct that occurred, and was completed, entirely in the past.” Dkt. 1, Compl. ¶ 1, No. 16-cv-05600-PD; Dkt. 1, Compl. ¶ 1, No. 16-cv-05599-PD.

Contrary to the FTC’s arguments, no additional factual development is necessary to decide these Actions, which confirms the legal nature of the issues. *See Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985). Indeed, the FTC conceded in its Original Action that the conduct it is challenging

occurred wholly in the past: (1) the Opana ER and Lidoderm settlement agreements were completed years prior to the FTC’s Original Action; and (2) generic versions of Lidoderm and Opana ER have since entered the market. *See* Dkt. 1, Compl. ¶¶ 1-4, No. 16-cv-01440-PD. Thus, there is no likelihood that the alleged anticompetitive conduct will recur, and the FTC admitted that it already possesses the information it needs to make this determination. *See* Dkt. 114 at 3 & n.2, No. 16-cv-01440-PD (averring that as of October 7, 2016, “the FTC [was] able to provide . . . under seal” materials that could establish its statutory authority to sue in federal court). This Court need decide only the purely legal question of whether the FTC Act authorizes the original or threatened suits.¹³

2. Failure To Hear The Declaratory Judgment Actions Would Create Undue Hardship.

The undue hardship analysis looks to whether the “effects [are] felt in a concrete way by the challenging parties.” *Abbott Labs.*, 387 U.S. at 148-49. In the typical case, this sort of hardship exists where a plaintiff is faced with the dilemma of complying with a regulation or facing an enforcement action. *See id.* at 152. This scenario is inapplicable here because *Abbott Labs* applies only to “pre-enforcement review,” *see* Mot. at 16, whereas Plaintiffs in these Actions have

¹³ If the Court were to hold that the FTC Act provides no such authority, the subsidiary issues raised in the Actions—*i.e.*, the FTC’s ability to seek monetary relief and the timeliness of its claims regarding Opana ER—would be moot.

already faced an enforcement action. Of course, if the mere possibility of an enforcement action creates “undue hardship,” then facing an actual enforcement action—as Plaintiffs do here—is more than sufficient. *See Eagle-Picher Indus., Inc.*, 759 F.2d at 918 (“[M]echanical application of the second prong of the *Abbott Laboratories* test could work mischief in such a situation.”).

Further, the FTC ignores the unnecessary hardship its preferred litigation path would place on the judicial system. *See Payne Enters., Inc. v. United States*, 837 F.2d 486, 493 (D.C. Cir. 1988) (“[T]he hardship prong of the *Abbott Laboratories* test is not an independent requirement divorced from the consideration of the *institutional interests of the court* and agency.” (emphasis added)). The FTC seeks to have two separate courts hear and resolve issues that have already been briefed before this one. This defies common sense and would create additional hardship for all involved.

V. CONCLUSION

Plaintiffs respectfully request that the Court deny the FTC’s motion.

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CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of January, 2017, Plaintiffs' Opposition to Defendant's Motion to Dismiss was filed electronically and served on counsel of record via the Court's CM/ECF Filing System.

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